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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,894	11/21/2000	Karl-Heinz Buettgen	C 2109 COGG	2009

23657 7590 01/24/2003

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EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 01/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/717,894Applicant(s)
Buettgen et al.Examiner
Irene MarxArt Unit
1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Dec 12, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachments
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: _____
- Claim(s) objected to: _____
- Claim(s) rejected: _____
- Claim(s) withdrawn from consideration: _____
8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

IRENE MARX
PRIMARY EXAMINER
ART UNIT 1651

Interview Summary

Application No.

09/717,894

Applicant(s)

Buettgen et al.

Examiner

Irene Marx

Art Unit

1651



All participants (applicant, applicant's representative, PTO personnel):

(1) Irene Marx

(3) _____

(2) Mr. Trzaska

(4) _____

Date of Interview Jan 9, 2003Type: a) ☒ Telephonic b) ☐ Video Conferencec) ☐ Personal [copy is given to 1) ☐ applicant 2) ☐ applicant's representative]Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No. If yes, brief description:

Claim(s) discussed: _____

Identification of prior art discussed: _____

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Acknowledged receipt of after final amendment. A response will be sent as soon as possible.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☒ It is not necessary for applicant to provide a separate record of the substance of the interview (if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached

IRENE MARX
PRIMARY EXAMINER
ART UNIT 1651

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

The arguments after final filed 12/12/02 is acknowledged. Claims 1-10 are being considered on the merits.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of Gatfield *et al.* and Lepper *et al.*, the cited and relied upon references which make up the state of the art with regard to the claimed invention. As correctly noted by applicants (Response, page 3, second paragraph, Lepper *et al.* teach a method of treating a triglyceride with a lower alcohol with a catalyst and treating the product again with a lower alcohol and catalyst thereby producing a product having a lower acid number. The sole difference is the use of an acidic catalyst rather than a lipase. However, the Gatfield *et al.* reference is directed a method of treating a triglyceride, Stillingia oil, with the lower alkanol, ethanol, to produce a product which cannot be readily distinguished over the pre-esterification product having a lower acid number produced in the process using an acidic catalyst or the process of the instant invention. See, e.g., Example 2, wherein *C. antarctica* lipase is used. From Lepper *et al.* it can reasonably be concluded that the esterification reaction of a triglyceride or oil containing fatty acids with a short chain monoalcohol using a suitable catalyst will result in a product having a lower acid value. See, e.g., example 1, wherein coconut oil is reacted.

Applicant's argument that Gatfield teaches transesterification rather than esterification is noted. However, the basis for this argument is unclear, since the same substrate, coconut oil, is treated with the same type of alcohol and the same enzyme. Note also that at col. 1, lines 19 to 25, the constituents of Stillingia oil are disclosed. This material contains 7% by weight palmitic acid and about 70% of C-18 fatty acids (about 40% linolenic acid). It also contains 5% of esters of a decadienoic acid. It appears that these are the esters that undergo transesterification, while the fatty acids undergo esterification. Therefore the process appears to be substantially the same

and would reasonably be expected to produce the same result, even if it is called "transesterification" rather than "esterification". Similarly, since the same process steps are used, the same results of reducing the acid number would be expected to occur at least to some extent. In addition, the claims as written fail to exclude transesterification, since they are drafted in terms of the open language "comprising". The arguments directed to "free fatty acids" in triglycerides appear misleading, since the fatty acids are bound to glycerol, for example, and the method is directed to the reaction of a triglyceride.

Applicants argue that the substitution of the acidic catalyst of Lepper with Gatfield's lipase is neither taught, suggested or motivated in either reference and therefore is impermissible for establishing a *prima facie* case of obviousness. Contrary to applicant's argument, it is well established that motivation for combining references need not come from the references themselves, as long as applicant's disclosure is not improperly used in a hindsight reconstruction of the claimed invention. *See Ex parte Levengood*, 28 USPQ2d 1300 (1993), at 1301. ("Motivation for combining the references need not be explicitly found in the references themselves. Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness.")(Citations omitted.)

Applicant's arguments regarding the unpredictability of enzymes in the esterification process taught by Lepper are noted. However, it is in the Gatfield reference that the teachings providing compelling motivation to use lipase are found, since it is environmentally friendly, economic, easy to produce and may be recycled. Moreover, the arguments presented are inconsistent with the invention as claimed, directed to the use of any lipase, except for claim 8. The arguments are also inconsistent and contrary to the disclosure at Specification, bridging paragraph between pages 4 and 5. The Gatfield reference is relied upon because it recommends the use of precisely the same lipase as applicant uses in the Examples and in claim 8, i.e. the lipase from *Candida antarctica*, including NOVOZYM^R 435.

In response to applicant's contentions that adjustment of the claim designated concentrations of substrate, alcohol and lipase does not constitute mere optimization, it is noted that only in claims 7 and 9 is any amount stipulated, and even then only in broad ranges. In

addition, the process of Example 4 of Gatfield uses 5% lipase by weight of triglyceride, as in claim 9. With respect to the concentration range of alcohol, the Gatfield *et al.* reference uses a concentration of 20%, which clearly corresponds to the "excess" required in claim 1. Moreover Lepper *et al.* explains that the quantity of alcohol used has a positive effect on the velocity and completeness of the esterification of the free fatty acids in the esterification process. However, due to the cost of the alcohol, the reference recommends curtailing the amount of alcohol (Col. 6, lines 39-51). Therefore, the use of 1-10% lower alcohol rather than 20% would be have been a *prima facie* obvious adjustment to one of ordinary skill in the art at the time the claimed invention was made in view of the reference teachings.

The arguments presented fail to demonstrate error in the Examiner's position that it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Gatfield *et al.* by subjecting the pre-esterification product to further lipase treatment in the presence of ethanol or another alkanol for the expected benefit of maximizing the concentration of valuable esterified products and reducing the acid value of the mixture, as suggested by the teachings of Lepper *et al.*.

Therefore the rejection is deemed proper and it is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.



Irene Marx
Primary Examiner
Art Unit 1651